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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/810,768

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William F. Niland

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EXAMINER

DEMILLE, DANTON D

ART UNIT

PAPER NUMBER

3771

MAIL DATE

DELIVERY MODE

01/22/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/810,768	Applicant(s) NILAND ET AL.	
	Examiner Danton DeMille	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-18,20-39 and 42-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-18,20-39 and 42-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/28/8</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Drawings***

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 422. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the delivery tube, fitting and nasal cannula must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must

be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

Claims 16-18, 20-39, 42-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims include a supply unit and a delivery tube assembly that appear to be elements 402 and 404 respectively as shown in figure 3. It has been assumed the claims are drawn to the embodiment of figure 3.

It is not clear if there is support in the original disclosure for the supply unit configured to deliver heated and humidified gas. As understood, the supply unit 402 delivers heated water through a heater 422, not shown, from a water bag 416. Humidified gas is provided through exchanger 410 from gas source 406. There appears to be no support for the supply unit to deliver "heated and humidified gas" or heats a breathing gas and combines the breathing gas with water vapor as claimed.

The delivery tube assembly is recited as having a delivery tube however, there appears to be no support in the original disclosure for the delivery tube.

The delivery tube assembly is recited as having a fitting however, there appears to be no support in the original disclosure for the fitting.

The delivery tube assembly is recited as configured to transfer heat to the heated and humidified gas received from the supply unit however, there appears to be no support in the original disclosure for this.

The system is recited as having a nasal cannula however, there appears to be no support in the original disclosure for the nasal cannula.

In claim 18 there appears to be no support in the original disclosure for the supply unit being configured to deliver humidified gas at a flow rate above about 20 liters per minute.

In claims 30, 31, 33 there appears to be no support in the original disclosure for a method for delivering heated and humidified gas to a neonatal patient.

In claim 32 there appears to be no support in the original disclosure for delivering “only” heated and humidified gas through the cannula. The original disclosure would appear to comprehend the ability of the device to deliver gas that is not humidified by not allowing the passage of liquid water. There doesn’t appear to be support for delivering “only” heated and humidified gas or why this is now critical or what is the novel feature of delivering “only” heated and humidified gas.

In claim 34 there appears to be no support in the original disclosure for fluid flowing “through and reverses direction in the delivery tube”.

In claims 36, 39, 42 there appears to be no support in the original disclosure for the fluid flow to insulate the breathing gas prior to humidifying the breathing gas.

Claim Rejections - 35 USC § 112

Claims 42-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The penultimate paragraph of claim 42 recites the step of insulating the heated and humidified breathing gas however, the end of the paragraph recites the fluid heats the heated and humidified breathing gas. The paragraph appears to contradict itself.

To any extent the claims are understood and appear supported by a clear and complete disclosure the following appears to be appropriate.

Claim Rejections - 35 USC § 103

Claims 16-18, 20-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniell et al. (US 6,050,260) in view of Ko et al. '527.

Daniell teaches, for example, an apparatus and method including a supply unit in figure 1 configured to deliver heated and humidified gas. A delivery tube assembly 3 having a fitting at the proximal end of the delivery tube coupled to the outlet 4. The delivery tube assembly 3 is configured to transfer heat to the heated and humidified gas by including a heating means or heater wires, column 3, lines 51-54, to reduce condensation of humidified gases within the conduit. Daniell teaches a nasal mask however, using other conventional means to deliver pressurize air to the patient would have been obvious. Ko exemplifies the convention of using cannulas to deliver pressurized air to the patient. It would have been obvious to one of ordinary

skill in the art to modify Daniell to use a nasal cannula as taught by Ko instead of a nasal mask as an obvious equivalent alternative means for performing the same function.

Providing releasable coupling for assembling and disassembling the plurality of conduits within the system of the prior art would have been obvious to one of ordinary skill in the art for assembling, disassembling or cleaning.

Regarding claims 27-29, providing a supplemental water source to refill the water chamber 6 would have been obvious to one of ordinary skill in the art so that the user does not have to continuously refill the water chamber 6.

Regarding claims 30, 31, 33, using the device for a neonatal patient would have been obvious in order to comprehend different sized patients.

The exact flow rates and humidity levels used during operation of the device is well within the realm of the practitioner of ordinary skill in order to compensate for practical considerations of intended use dependent on the requirements for each individual patient.

Claims 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 16-18, 20-39 above, and further in view of Verkaart.

Daniell teaches that the delivery tube can include any conventional heating means and gives an example of using heating wires. Any other conventional heating means within the delivery tube would have been an obvious to one of ordinary skill in the art. Verkaart exemplifies such a convention by using a fluid circulation system. It would have been obvious to one of ordinary skill in the art to further modify Daniell to use a fluid circulation system as taught by Verkaart as an obvious equivalent means for performing the same function.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danton DeMille whose telephone number is (571) 272-4974.

The examiner can normally be reached on M-F from 8:30 to 6:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu, can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

22 January 2009

/Danton DeMille/

Danton DeMille
Primary Examiner
Art Unit 3771